Product Design Specifications
BME 402: Endoscopic Carpal Tunnel Release Surgical Simulator
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Problem Statement:

All surgical procedures require practice and repetition in order to achieve optimal outcomes. Currently, carpal tunnel syndrome release surgery is only performed on cadavers or live patients. Therefore, the cost of practicing this procedure is quite high. To reduce this cost and improve surgical performance, an ideal solution is an anatomically accurate simulator with realistic haptics. Our simulation device will not only reduce costs, but also improve patient safety and maximize hospital resources.

Although many surgical simulators are in use, no current devices incorporate haptics and realistic visuals simultaneously for a low cost. Hybrid surgical simulators allow for interaction between virtual and physical models where the surgeon views virtual images on a monitor but uses real instruments, but currently only exist for laparoscopic surgery. Until now, no device has existed for simulating endoscopic carpal tunnel surgery that employs the hybrid approach while providing an accurate anatomical model.

Our design is marketable to hospitals around the country as it reduces the need for cadaver utilization and increases the frequency at which surgeons are able to practice the procedure. Costs of simulation systems can range anywhere from $75,000 for basic models, to over $100,000 for advanced, high end models. Currently, the unit cost of our device is approximately $900 with a possible selling price of $10,000. Not only is this a considerable reduction in cost, but our design could also serve as a model for the development of subsequent simulators, opening tremendous commercial opportunity across surgical fields.

Our device consists of a silicone-based hand model, an endoscope fitted with a circuit board housing three LEDs, and a receiver which reads three-axis position data from the LEDs. This combines both a mechanical model and software images to create a realistic training tool. Our design has been tested for both accuracy and range of distance readings. Feedback from experienced surgeons was implemented to help optimize the prototype and produce realistic haptics throughout the simulation

1. Design Requirements:

The device must meet all of the client requirements

a. Performance requirements: The force feedback provided by the hand model should replicate the forces experienced by the surgeon when performing the procedure. An increased resistance should be felt when the blade is deployed. Transition between endoscope images should be smooth.
b. Safety: Device should not cause any harm to the surgeon or other connected devices involved with the simulation.
c. Accuracy and Reliability: Signaling device should be able to detect position of the endoscope within 1 mm. The tracking system should maintain accuracy of position throughout multiple

simulations. The force feedback mechanism should provide a consistent amount of force in each simulation.

d. Life in Service: Simulator should be able to withstand repeated uses as a training tool for surgeons for a minimum of 5 years.
e. Operating Environment: Device will be used at room temperature and standard humidity. The simulator will not be used in the operating room so does not need to be sterilized.
f. Ergonomics: The haptic feedback from the hand model should replicate the forces felt while performing the actual surgery. The external circuit should be positioned so that does not interrupt the surgical technique. The method of device tracking should not alter the physical components of the endoscope or its blade attachment.
g. Size: Hand model should be life size and the incision site should be 5 mm proximal of the distal wrist crease. The carpal tunnel should be 1 cm in diameter. The transverse carpal ligament should be 5 mm thick. The ligament corrugations are 1 mm in height and thickness with 1 mm of spacing between consecutive corrugations.
h. Materials: Hand material looks like and has mechanical properties similar to carpal tunnel tissue. The force feedback mechanism should be compatible with the silicone material used in the hand model.

2. Production Characteristics:

    a. Quantity: One working prototype is necessary.
    b. Target Product Cost: $1000

3. Miscellaneous:

    a. Standards and Specifications: No specific standards because prototype is only used in simulation as a training tool, not actual surgery.
    b. Customer: The client will use the device to train other surgeons on the endoscopic carpal tunnel release procedure. The tracking system will be incorporated with a virtual environment created by the client in Adobe Director.
    c. Patient-related Concerns: None
    d. Competition: A current device involving minimally invasive surgeries called TrEndo. It creates a physical connection between the tracking element and the surgical device, however has not been applied to carpal tunnel surgery.